

**REMARKS**

The claims have been amended to resolve issues raised by the Examiner under 35 U.S.C. 112. Applicant notes that claims 1 and 21 have been amended so that the expression "15-keto-16-mono or dihalogen prostaglandin E1 compound" is not used. Also, in Formula (II), A is limited to "-COOH or a salt, ester, or amide thereof", and the "heterocyclic group" and "heterocyclic-oxy group" recitations are deleted from the definitions of R<sub>1</sub> and R<sub>3</sub>. In the dependent claims, compounds are limited by introducing limitation in the definitions of variables. Also, Applicant has deleted the recitation "to reduce body weight" from claim 21 since it seemed redundant. In addition, claims have been added directed to preferred embodiments of the present invention.

Entry of the above amendments is respectfully requested.

**Objection to Claim 26**

On page 2 of the Office Action, in paragraph 5, the Examiner has objected to claim 26 as being dependent upon a rejected base claim, but has indicated that it would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant thanks the Examiner for indicating that claim 26 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In view of the Examiner's indication, Applicant has redrafted claim 26 as an independent claim and, therefore, Applicant believes this objection has been overcome. Accordingly, withdrawal of this objection and allowance of claim 26 is respectfully requested.

**Rejection under 35 U.S.C. 112, Second Paragraph**

On page 3 of the Office Action, in paragraph 7, claims 1, 5, 7, 11-13, 21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner's position is that claims 1 and 21 recite the "A" substituent of formula (II) "is -CH<sub>3</sub>, or -CH<sub>2</sub>OH, -COCH<sub>2</sub>OH, -COOH or a salt, ether, ester or amide thereof", but it is unclear what an ether of the -COOH moiety is.

In response, and to advance the prosecution, "ether" has been deleted from the definition of A. Accordingly, withdrawal of this rejection is respectfully requested.

**Written Description Rejection under 35 U.S.C. 112, First Paragraph**

On page 3 of the Office Action, in paragraph 8, claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner's position is that claim 25 recites "a compound which is 13,14-dihydro-15-keto-16,16-difluoro PGE1 or a salt, ether, ester or amide thereof" and while the specification discloses an ether, ester or amide of -COOH when the substituent A of formula (II) is -COOH, there is insufficient written basis in the specification for an ether, ester or amide at any other position in formula (II).

In response, and to advance the prosecution, "ether" has been deleted from claim 25. Applicant submits that the amended claim as reasonably construed has basis in the specification. Accordingly, withdrawal of this rejection is respectfully requested.

**Enablement Rejection under 35 U.S.C. 112, First Paragraph**

On page 5 of the Office Action, in paragraph 9, claims 1, 5, 7, 11-13, 21, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the weight of obese patients by the administration of a 15-keto-16-mono or dihalogen prostaglandin E1 (PGE1) compound, a salt thereof, or an ester or amide of the  $\alpha$  chain terminal carboxylic acid, does not reasonably provide enablement for reducing the weight of obese patients by the administration of multitude of prostaglandin compounds as defined by the rejected claims.

The Examiner's position is basically that the number of compounds defined by formula (I) is still very large and the chemical structure of compounds defined by the claims is quite varied, but the specification has only provided guidance and a working example for a method of reducing body weight in humans by the oral administration of a single prostaglandin compound, 13,14-dihydro-15-keto-16,16-difluoro-PGE1. The Examiner considers that one of skill in the art would not reasonably expect compounds within the full breadth of the claims, such as the structures identified by the Examiner on pages 8 and 9 in the Office Action, to have any physiological activity similar to 13,14-dihydro-15-keto-16,16-difluoro-PGE1, especially when one considers that the comparatively minor change in structure between 13,14-dihydro-15-keto-16,16-difluoro-PGE1 and the compound 13,14-dihydro-15-keto-16-fluoro-PGE2 disclosed by Ueno et al. results in a significant change in weight reduction when administered to subjects. Accordingly, the Examiner concludes that one of skill in the art would have to undergo an undue amount of experimentation to use the claimed compounds for the claimed methods.

In response, Applicant notes that the claims have been amended to limit the scope around the compound used in the example. On page 8-9 of the Office Action, the Examiner indicates

some compounds having heterocyclic moieties and, therefore, heterocyclic moieties are excluded from the amended claims.

Thus, Applicant submits that the amended claims are enabled, and withdrawal of this rejection is respectfully requested.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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CUSTOMER NUMBER

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Respectfully submitted,



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